K122696

CardinalHealth

JAN 31 2013

510(K) SUMMARY
POWDER-FREE NITRILE EXAMINATION GLOVES (COOL BLUE)
(A510(k) summary information in accordance with the requirements of 21 CFR 807.92)

Applicant: Cardinal Health
1430 Waukegan Road
McGaw Park, IL 60085
Establishment Registration Number: 1423537
Regulatory Affairs Contact: Tatyana Bogdan, RAC
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Summary Prepared: October 21, 2012

Trade Name: Powder-Free Nitrile Exam Gloves (Cool Blue)
Common Name: Exam Gloves
Classification Name: Patient Examination Gloves
Classification Panel: General Hospital
Regulation: 21 CFR 880.6250
Product Code(s): LZA
Legally marketed device(s) to which equivalence: Nitrile Cornflower Blue Powder-Free Examination Gloves Tested for Use with Chemotherapy Drugs previously cleared under 510(k) K103249 (product code LZA);
Reason for 510(k) Submission: New device

Device Description: The proposed device is a disposable device intended for over the counter use and is provided powder-free and non-sterile. These patient examination gloves are formulated using Nitrile. Gloves are not made with natural rubber latex. The glove color is cool blue.

Intended Use: A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

<table>
<tr><th colspan="3">Summary of the technological characteristics of the device compared to the predicate device</th></tr>
<tr><td>Characteristic</td><td>New Device
Powder-Free Nitrile Examination Gloves (Cool Blue)</td><td>Predicate Device
Nitrile Cornflower Blue Powder-Free Examination Gloves Tested for Use with Chemotherapy drugs (K103249)</td></tr>
<tr><td>Material Composition</td><td>Nitrile</td><td>Nitrile</td></tr>
<tr><td>Design</td><td>Powder-Free
Ambidextrous
Beaded Cuff
Non-Sterile</td><td>Powder-Free
Ambidextrous
Beaded Cuff
Non-Sterile</td></tr>
<tr><td>Color</td><td>Cool Blue</td><td>Cornflower Blue</td></tr>
<tr><td>Intended Use / Indications for Use</td><td>A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.</td><td>A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

<table>
<tr><th>Chemotherapy Drug and Concentration</th><th>Minimum Breakthrough Detection Time in Minutes, 0.01 µg/cm^2/minute</th></tr>
<tr><td>Carmustine (BCNU) (3.3 mg/ml)</td><td>7.28</td></tr>
<tr><td>Cisplastin, (1.0mg/ml)</td><td>>240</td></tr>
<tr><td>Cyclophosphamide (20 mg/ml)</td><td>>240</td></tr>
<tr><td>Doxorubicin HCl (2.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Etoposide (Toposar) (20 mg/ml)</td><td>>240</td></tr>
<tr><td>5-Fluorouracil (50 mg/ml)</td><td>>240</td></tr>
<tr><td>Methotrexate (25 mg/ml)</td><td>>240</td></tr>
<tr><td>Paclitaxel (Taxol) (6.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Thiotepa (10 mg/ml)</td><td>2.67</td></tr>
</table>

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time of less than 30 minutes: Carmustine (BCNU) (3.3 mg/ml), Thiotepa (10 mg/ml)</td></tr>
<tr><td>Dimensions & Physical Properties</td><td>Meets ASTM D6319</td><td>Meets ASTM D6319</td></tr>
</table>

Freedom from Holes	AQL meets 21CFR 800.20 & ASTM D6319 requirements	AQL meets 21CFR 800.20 & ASTM D6319 requirements
Powder Residual	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D6319	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D6319

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
Biocompatibility:		
Primary Skin Irritation	ISO 10993-10	Gloves are non-irritating.
Guinea Pig Maximization	ISO 10993-10	Gloves do not display any potential for sensitization.
Physical Characteristics:		
Dimensions	ASTM D6319	Meet requirements
Physical Properties	ASTM D6319	Meet requirements
Freedom from Holes (Water Leak test)	21 CFR 800.20 & ASTM D6319	Tested in accordance with ASTM D5151 test method with acceptable results
Powder Residual	ASTM D6319	Tested using ASTM D6124 test method. Gloves meet powder level requirements for "Powder-Free" designation per ASTM D6319. Results generated values < 2mg of residual powder per glove.

Comparative Performance Information Summary

Characteristic	Requirement	**New Device**	**Predicate Device**
Biocompatibility:	ISO 10993-1	Meets requirements	Meets requirements
Primary Skin Irritation	ISO 10993-10	Pass	Pass
Guinea Pig Maximization	ISO 10993-10	Pass	Pass
Dimensions	ASTM D6319	Meets requirements	Meets requirements
Physical Properties	ASTM D6319	Meets requirements	Meets requirements
Freedom from Holes (Water Leak Test)	21CFR800.20, ASTM D6319	Meets requirements	Meets requirements
Powder Residual	ASTM D6319	Meets requirements	Meets requirements

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
Clinical data is not required.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The Powder-Free Nitrile Examination Gloves (Cool Blue) meet the technological characteristics of ASTM D6319 performance standard. They are as safe, as effective, and performed as well as the legally marketed device identified in this 510(k) summary except for the chemotherapy permeation claim for which the new device was not tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31 2013

Cardinal Health, Incorporated
C/O Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Incorporated
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K122696
Trade/Device Name: Powder-Free Nitrile Exam Gloves (Cool Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: January 18, 2013
Received: January 22, 2013

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

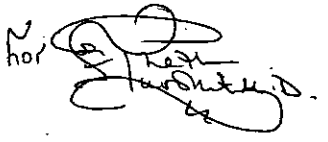
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122696

Device Name: Powder-Free Nitrile Exam Gloves (Cool Blue)

Indications for Use: A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ramesh C. Panguluri -S
2013.01.28 11:42:53 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122696